SURGICAL IMPLANT DEVICES AND METHODS FOR THEIR MANUFACTURE AND USE

CROSS REFERENCE TO RELATED APPLICATION

This application claims the benefit of U.S. Provisional Patent Application No. 61/222,646, filed Jul. 2, 2009, the disclosure of which is incorporated by reference herein in its entirety.

FIELD OF THE INVENTION

The present disclosure relates to the field of surgical implant devices and method for their manufacture and use. In particular, this disclosure relates to medical devices applicable to vascular surgery and the treatment of aneurysms or other luminal defects in other anatomic conduits.

BACKGROUND OF THE INVENTION

Medical and surgical implants are often placed in anatomic spaces where it is desirable for the implant to conform to the unique anatomy of the targeted anatomic space to secure a seal therein, preferably without disturbing or distorting the unique anatomy of said targeted anatomic space.

While the lumens of most hollow anatomic spaces are ideally circular, in fact the cross-sectional configurations of most anatomic spaces are at best ovoid, and may be highly irregular. Lumenal irregularity may be due to anatomic variations and/or to pathologic conditions that may change the shape and topography of the lumen and its associated anatomic wall.

Examples of anatomic spaces where such implants may be deployed include, but are not limited to, blood vessels, the heart, other vascular structures, vascular defects, the trachea, the oropharynx, the esophagus, the stomach, the duodenum, the ileum, the jejunum, the colon, the rectum, ureters, urethras, fallopian tubes, biliary ducts, pancreatic ducts, or other anatomic structures containing a lumen used for the transport of gases, blood, or other liquids or liquid suspensions within a mammalian body.

Among vascular effects that are addressed by some preferred embodiments of the present disclosure are thoracic and abdominal aortic aneurysms.

In order for a patient to be a candidate for existing endograft methods and technologies, a proximal neck of at least 15 mm of normal aorta must exist between the origin of the most inferior renal artery and the origin of the aneurysm in the case of abdominal aneurysms or the left subclavian artery for thoracic aortic aneurysms in order to permit an adequate seal. Similarly, at least 15 mm of normal vessel must exist distal to the distal extent of the aneurysm for an adequate seal to be achieved.

Migration of existing endografts has also been a significant clinical problem, potentially causing leakage and re-vascularization of aneurysms and/or compromising necessary vascular supplies to arteries such as the carotid, subclavian, renal, or internal iliac vessels. This problem has been partially addressed by some existing endograft designs, in which barbs or hooks have been incorporated to help retain the endograft at its intended site. However, these existing endograft designs are not removable and repositionable once they are deployed. Thus, once such an endograft has been placed, open surgery is necessary if there is failure due to leakage or undesired occlusion of other vascular structures.

Because of the limitations imposed by existing vascular endograft devices and endovascular techniques, approximately eighty percent of abdominal and thoracic aneurysms repaired in the U.S. are still managed though open vascular surgery, instead of the lower morbidity of the endovascular approach.

SUMMARY OF THE INVENTION

Implant devices according to the present disclosure are provided with one or more improvements that increase the ability of such an implant to be precisely deployed or redeployed, with better in situ accommodation to the local anatomy of the targeted anatomic site, and/or with the ability for post-deployment adjustment to accommodate anatomic changes that might compromise the efficacy of the implant.

One aspect of the present disclosure is directed towards novel designs for endovascular implant grafts, and methods for their use for the treatment of aortic aneurysms and other structural vascular defects. A sealable, repositionable endograft system for placement in a blood vessel is disclosed, in which an endograft implant comprises a non-elastic tubular implant body with an elastic proximal ends and an elastic distal end(s). Both the elastic proximal and distal ends in an implant according to the present disclosure further comprise one or more circumferential sealable collars and one or more variable sealing device, capable of controllably varying the expanded diameter of said collar upon deployment to achieve the desired seal between the collar and the vessel's inner wall. An endovascular implant according to the present disclosure further comprises a central lumen and one or more control leads extending distally from releasable connections with each variable sealing device. Embodiments of endovascular implants according to the present disclosure may further be provided with retractable retention tines or other retention devices allowing an implant to be repositioned before final deployment. An endograft system according to the present disclosure further comprises a delivery catheter with an operable tubular sheath, capable of housing a folded or compressed endograft implant prior to deployment and capable of retracting or otherwise opening in at least its proximal end to allow implant deployment, said sheath sized and configured to allow its placement via a peripheral arteriotomy site, and of appropriate length to allow its advancement into the thoracic or abdominal aorta, as required for a specific application.

Post-implantation remodeling of the aortic neck proximal to an endovascular graft (endograft) has been reported. While this phenomenon may be due to aortic wall injury caused by the over-dilatation (typically 110%) of the aorta to deploy the metallic lattice that supports such endografts, existing endograft technology does not allow for the management of this condition without placement of an additional endograft sleeve to cover the remodeled segment, again requiring the over-dilatation for deployment.

Endografts of the present disclosure do not require balloon over-dilatation for their deployment. Moreover, the improvements in implant design described herein allow for better accommodation by the implant of the local anatomy, as opposed to altering the local anatomy to conform to the implant as is the presently accepted practice. Finally, implants with improvements of the present disclosure may be provided with means to change the implant configuration post-initial deployment, allowing for manual adaptation to any future anatomic remodeling at the implantation site.